

OCT 28 2005

K 052982

510(k) Summary - cobas Elecsys® Prolactin II CalSet

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

**Submitter
name, address,
contact** Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3532

Contact person: Randy Johnson

Date prepared: October 21, 2005

Device Name Proprietary name: Roche Diagnostics cobas Elecsys® Prolactin II CalSet

Common name: Prolactin II CalSet

Classification name: Calibrator, Secondary

**Device
description** The cobas Elecsys® Prolactin II CalSet consists of a lyophilized buffered equine serum matrix with added recombinant prolactin in two concentration ranges. The CalSet can be used with all reagent lots.

510(k) Summary - cobas Elecsys® Prolactin II CalSet, continued

Intended use Elecsys Prolactin II CalSet is used for calibrating the quantitative Elecsys Prolactin II assay on the Elecsys immunoassay systems.

Predicate Device The cobas Elecsys® Prolactin II CalSet is equivalent to other devices legally marketed in the United States. We claim equivalence to the Elecsys Prolactin CalSet (K964748).

Device Comparison The table below illustrates the similarities between the Elecsys Prolactin (K964748) and the cobas Elecsys Prolactin II CalSet (modified device).

Topic	Elecsys® Prolactin (K964748)	cobas Elecsys® Prolactin II CalSet (Modified Device)
Intended use	Elecsys Prolactin CalSet is used for calibrating the quantitative Elecsys Prolactin assay on the Elecsys immunoassay systems.	Elecsys Prolactin II CalSet is used for calibrating the quantitative Elecsys Prolactin II assay on the Elecsys immunoassay systems.
Matrix	Buffer/protein	Buffered equine serum
Storage form	Liquid	Lyophilized
Levels	Low: approx. 2 µIU/mL High: approx. 2,000 µIU/mL	Same
Standardization	Standardized using the 3 rd IRP WHO Reference Standard 84/500	Same
Stability	Unopened: at 2-8°C up to the expiration date. Opened: at 2 - 8°C; 8 weeks on the analyzers, up to 5 hours in total	Unopened: at 2-8°C up to the expiration date. Opened: at -20°C; 3 months (freeze only once) on the analyzers at 20 - 25°C; use only once



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 28 2005

Randy Johnson MT (ASCP)
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
PO Box 50416
Indianapolis, IN 46250

Re: k052982
Trade/Device Name: cobas Elecsys Prolactin II CalSet
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: October 21, 2005
Received: October 24, 2005

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

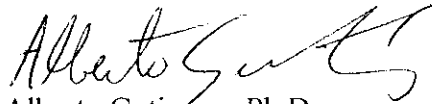
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K05 2982

Device Name: cobas Elecsys Prolactin II CalSet

Indications For Use:

Elecsys Prolactin II CalSet is used for calibrating the quantitative Elecsys Prolactin II assay on the Elecsys immunoassay systems.

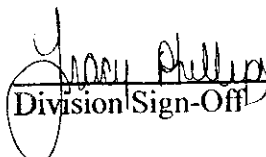
Prescription Use XXXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

Confidential

510(k) K05 2982